



[Billing Code 4140-01-P]

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### **Biennial Progress Report of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)**

**AGENCY:** Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH)

**ACTION:** Availability of Report

**SUMMARY:** The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces the availability of the *Biennial Progress Report 2010-2011: Interagency Coordinating Committee on the Validation of Alternative Methods*. The report was prepared in accordance with requirements of the ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3).

The *Biennial Progress Report* describes activities and progress by NICEATM and ICCVAM during the period from January 2010 through December 2011. During the past two years, NICEATM, ICCVAM, and ICCVAM member agencies contributed to the national and international endorsement and adoption of 14 new and updated alternative safety testing methods. Since ICCVAM was established, NICEATM, ICCVAM, and the ICCVAM member agencies have contributed to the regulatory acceptance of over 50 alternative methods that can be used to protect the health of people, animals, and the environment while reducing, refining, and replacing animal use.

The *Biennial Progress Report* is available on the NICEATM-ICCVAM website at <http://iccvam.niehs.nih.gov/about/ICCVAMrpts.htm>. Copies can also be requested from NICEATM (see “ADDRESSES”).

**ADDRESSES:** Requests for copies of the report should be sent by mail, fax, or email to Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2-16, Research Triangle Park, NC, 27709, (telephone) 919-541-2384, (fax) 919-541-0947, (email) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov). Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

**FOR FURTHER INFORMATION CONTACT:** Dr. William S. Stokes, NICEATM Director (phone 919-541-2384 or [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov)).

## **SUPPLEMENTARY INFORMATION:**

### **Background**

The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of NIEHS under NICEATM. The Act directs ICCVAM to coordinate interagency technical reviews of proposed new, revised, and alternative testing methods, including those that may reduce, refine (enhance animal well-being and lessen or avoid pain and distress), and replace animal use. ICCVAM prepares test method recommendations based on their scientific validity for regulatory safety testing, and submits these recommendations through the HHS Secretary (or designee) to U.S. Federal Agencies for adoption decisions.

A provision of the ICCVAM Authorization Act states that ICCVAM shall prepare “reports to be made available to the public on its progress under this Act,” with the first report to be completed within 12 months of enactment of the Act, and subsequent reports to be made

biennially thereafter. The fifth ICCVAM biennial progress report, which summarizes ICCVAM activities and accomplishments for the years 2010 and 2011, is now available.

### **Summary of Report Highlights**

The *Biennial Progress Report* describes new initiatives and progress by NICEATM and ICCVAM during the period from January 2010 through December 2011. During the past two years, NICEATM, ICCVAM, and ICCVAM member agencies contributed to the national and international endorsement and adoption of 14 new and updated alternative safety testing methods. Since ICCVAM was established, NICEATM, ICCVAM, and the ICCVAM member agencies have contributed to the regulatory acceptance of over 50 alternative methods that can be used to protect and improve the health of people, animals, and the environment while reducing, refining, and replacing animal use.

Selected highlights of NICEATM and ICCVAM activities described in the *Biennial Progress Report* include:

- On behalf of NICEATM and ICCVAM, NIEHS signed an amendment to an international cooperation agreement to add the Republic of Korea and its Korean Center for the Validation of Alternative Methods (KoCVAM) to the International Cooperation on Alternative Test Methods (ICATM). ICATM was established in 2009 by the United States, the European Union, Japan, and Canada to expedite the worldwide validation and regulatory acceptance of improved alternative test methods.
- The Organisation for Economic Co-operation and Development (OECD) adopted an international guidance document prepared by NICEATM and ICCVAM that describes how to use two cytotoxicity assays to reduce animal use for testing required to determine the

poisoning potential of chemicals. NICEATM led the international validation studies for the two cytotoxicity assays, which can reduce animal use by up to 50% for each test.

- Federal agencies and the OECD adopted several new versions and applications of the murine local lymph node assay (LLNA); an alternative method recommended by ICCVAM to assess whether substances may cause allergic contact dermatitis. The test methods reduce animal use for each test by 20- 40% and support expanded use of the LLNA for nearly all testing situations. Two new “green” versions of the LLNA were adopted that do not require radioactive reagents and will allow expanded use of the LLNA in laboratories worldwide.
- Federal agencies adopted ICCVAM recommended alternative test methods and procedures that will further reduce, refine, and replace animal use for eye safety testing. These include the routine use of medications to avoid most if not all pain and distress when it is necessary to use animals for required safety testing, and the first *in vitro* test method that can be used in a “bottom-up” approach to identify substances that are not considered eye hazards.
- NICEATM, ICCVAM, and their ICATM partners convened the first international workshop on alternative methods for human and veterinary vaccine potency and safety testing. The workshop reviewed the state of the science of alternative methods, and recommended priority research needed to develop improved and more efficient test methods that can also reduce, refine, and replace animal use. A focused workshop on human and veterinary rabies vaccine test methods was held in 2011 and additional focused workshops are planned for 2012 and 2013.
- ICCVAM completed international evaluation of an *in vitro* test method proposed as a screening test to identify substances with potential endocrine activity. The test method uses

engineered human cells to identify substances that induce or inhibit activation of the human estrogen receptor. Use of this test method may reduce the number of animals necessary for endocrine disruptor screening.

- NICEATM and ICCVAM convened two Best Practices for Regulatory Safety Testing Workshops to promote the use of improved and more efficient test methods that can also reduce, refine, and replace animal use. Participants learned how to select and use approved alternative methods to assess the safety or potential hazards of chemicals and products.

### **Background Information on ICCVAM and NICEATM**

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (enhance animal well-being and lessen or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM welcome the public nomination and submission of new, revised, and alternative test methods and strategies applicable to the needs of U.S. Federal agencies. Additional information about NICEATM and ICCVAM can be found on the NICEATM-ICCVAM website (<http://iccvam.niehs.nih.gov>).

Dated: June 4, 2012

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[FR Doc. 2012-14436 Filed 06/12/2012 at 8:45 am; Publication Date: 06/13/2012]